SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND DEBRA SCHOEN, R.Ph.

Come now Debra Schoen, R.Ph., ("Licensee") and the State Board of Pharmacy ("Board") and enter into this settlement agreement for the purpose of resolving the question of whether Licensee's license as a pharmacist will be subject to discipline. Licensee and the Board jointly stipulate and agree that a final disposition of this matter may be effectuated as described below pursuant to §621.045 Cum. Supp. 2006.

Pursuant to the terms of §536.060, RSMo 2000, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under §621.110, RSMo Cum. Supp. 2006, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Licensee acknowledges that she understands the various rights and privileges afforded her by law, including the right to a hearing of the charges against her, the right to appear and be represented by legal counsel; the right to have all charges against her proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against her; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against her and, subsequently, the right to a disciplinary hearing before the Board at which time she may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against her license. Being aware of these rights provided her by operation of law, Licensee knowingly and voluntarily

waives each and every one of these rights and freely enters into this settlement agreement and agrees to abide by the terms of this document, as they pertain to her.

Licensee acknowledges that she has received a copy of the investigative report and other documents relied upon by the Board in determining there was cause for discipline, along with citations to law and/or regulation the Board believes was violated. For the purpose of settlement only, Licensee stipulates that the factual allegations contained in this settlement agreement are true. Licensee further stipulates with the Board that based upon these findings, Licensee's license as a pharmacist, license number 041651, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621, Cum. Supp. 2006, and Chapter 338, RSMo Cum. Supp. 2006.

Joint Stipulation of Facts

1. The State Board of Pharmacy ("the Board") is an agency of the State of Missouri created and established pursuant to § 338.110 and § 338.140, RSMo 2000, for the purpose of executing and enforcing provisions of Chapter 338, RSMo.

2. On or about January 16, 1985, Debra Schoen ("Licensee") was licensed by the Board as a pharmacist, license number 041651. Licensee's Missouri license was at all times relevant herein, and is now, current and active.

3. For at least the time period of October 21, 2005 through November 16, 2005, Licensee was a pharmacist at the Fitzpatrick Pharmacy (hereinafter "Pharmacy"), located at 15394 Manchester Road, Ellisville, Missouri.

4. On October 21, 2005, the Pharmacy filled an original prescription for the legend drug "Clindamycin" upon a valid prescription for an elderly resident in a long-term care facility with a serious bacterial skin infection.

5. The original prescription order read "Clindamycin HCL 150 mg. caps, TID – Dispense 21 – '0' refills."

6. Clindamycin is an antibiotic used to treat serious bacterial infections.

7. Clindamycin is known to cause serious, and sometimes fatal, pseudomembranous colitis, an inflammation of the lining of the bowels that interferes with normal bowel function, often associated with an overgrowth of a different bacteria, *clostridium difficille.*

8. The long term care facility faxed an order to the Pharmacy to refill the Clindamycin prescription for the resident on November 16, 2005.

9. Licensee erroneously refilled the prescription for the antibiotic, Clindamycin, on October 28, 2005, dispensing Clindamycin for a course of treatment extending to the seventh through fourteenth days of therapy, when the original prescription was for only seven (7) days, contained no refills and when no valid new prescription was received.

10. Licensee did not verify or check with either with the long term care facility or the physician concerning the validity of the refill order before filling it.

11. On November 16, 2005 Licensee made the final check of the third refill prescription for Clindamycin for the resident.

12. After nearly a month of receiving three (3) doses of Clindamycin per day, the resident developed severe diarrhea and abdominal pain, was transferred to the hospital and diagnosed with *Clostridium Difficile* Colitis.

13. On or about November 28, 2005, the resident died of Acute Colitis due to *clostridium difficile.*

14. The Clindamycin refill dispensed by Licensee on October 28, 2005 contained the name of the prescriber of the original Clindamycin prescriptions, when in fact, the prescriber had not authorized or ordered the refills.

15. Licensee and the Pharmacy have a relationship of professional trust and confidence with the Pharmacy's patients, particularly residents in long term care facilities, in that those patients and residents rely on Licensee as the pharmacist and the Pharmacy to perform their professional duties in compliance with the standard of care governing the practice of pharmacy and in a manner that protects the public safety.

16. Licensee and the Pharmacy have a relationship of professional trust and confidence with the long term care facility for whom they provide prescription services, in that the long term care facility relies on Licensee as the pharmacist and the Pharmacy to perform their professional duties in compliance with the standard of care governing the practice of pharmacy and in a manner that protects the public safety.

17. Licensee and the Pharmacy have a relationship of professional trust and confidence with the prescriber of legend drugs for residents in long term care facilities, in that those prescribers rely on Licensee as the pharmacist and the Pharmacy to perform their professional duties in compliance with the standard of care governing the practice of pharmacy and in a manner that protects the public safety.

CONCLUSIONS OF LAW

18. As a pharmacist, Licensee is responsible for the proper interpretation and evaluation of prescription orders. § 338.010.1, RSMo.

19. As a pharmacist, Licensee is responsible for the proper dispensing and labeling of drugs pursuant to a valid prescription. § 338.101.1, RSMo

20. The United States Food and Drug Administration ("FDA") has designated Clindamycin as a "legend drug" that may be dispensed only pursuant to a prescription and is not safe for use except under the supervision of a practitioner licensed by law to administer the drug. 21 U.S.C. § 353(b)(1) provides:

> (1) A drug intended for use by man which --
>
> > (A) because of its toxicity or other potentiality for harmful effect or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
> >
> > (B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

> shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

21. Clindamycin is a legend drug that requires a prescription prior to dispensing.

22. A prescription for the legend drug Clindamycin is valid in Missouri only if written by a licensed practitioner acting within the course and context of professional practice.

23. The Board adopted the regulation below, effective October 30, 2005, which provides in relevant part:

> Prescriptions processed by any classification of licensed pharmacy must be provided by a practitioner licensed in the United States authorized by law to prescribe drugs and who has performed a sufficient physical examination and clinical assessment of the patient. . .

20 CSR 220-2.020(11)

24. Section 338.059, RSMo states in relevant part:

> It shall be the duty of a licensed pharmacist ....to affix or have affixed by someone under the pharmacist's .... supervision a label to

each and every container provided to a consumer in which is placed any prescription drug upon which is typed or written the following information:

(1) The date the prescription is filled;

(2) The sequential number;

(3) The patient's name;

(4) The prescriber's directions for usage;

(5) The prescriber's name;

(6) The name and address of the pharmacy;

(7) The exact name and dosage of the drug dispensed;

(8) There may be one line under the information provided in subdivisions (1) to (7) of this subsection stating "Refill" with a blank line or squares following or the words "No Refill"

. . . .

25. Further, the Board's regulation at 4 CSR 220-2.018 establishes the requirements for valid prescriptions, which include:

(1) In order for a prescription to be valid for purposes of dispensing a medication by a pharmacy, it must conform to all requirements as outlined in sections 338.056 or 338.196, RSMo, and contain the following information:

(A) The prescription date and a unique, readily retrievable identifier;

(B) The name of the patient(s);

(C) The prescriber's name, if an oral prescription, signature if a written prescription;

(D) Any prescriber indication of name and dosage of drug, directions for use, name and dosage of drug dispensed;

(E) The number of refills, when applicable;

(F) The quantity dispensed in weight, volume or number of units;

(G) The initials or name of the pharmacist responsible for processes in dispensing or compounding of the prescription;

(H) Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills or authority to substitute a drug;

. . . .

(2) The information specified in section (1) shall be required and recorded on all handwritten, telephone, oral and electronically produced prescriptions that are processed for dispensing by a pharmacist/pharmacy.

4 CSR 220-2.018

26. The Board's regulation at 4 CSR 220-2.140(5) further provides the standard for pharmacies and pharmacists when prescription services are provided to residents in long term care facilities:

> A prescription drug order is defined for the purpose of this rule as an order originating from a long-term care facility that is initiated by a prescriber and entered into the patient's medical record by the prescriber or qualified personnel for the purpose of initiating or renewing an order for a medication or device. All prescription drug orders shall comply with 4 CSR 220-2.018.

4 CSR 220-2.140(5)

27. Section 196.015(1), RSMo states in relevant part:

> The following acts and the causing thereof within the state of Missouri are hereby prohibited:
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> (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
>
> (2) The adulteration or misbranding of any food, drug, device, or cosmetic;
>
> . . . .

28. Section 196.100.1, RSMo states in relevant part:

> Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.

29. The federal labeling requirements outlined at 21 U.S.C.A. § 352 provide in relevant part:

> A drug or device shall be deemed to be misbranded--
>
> (a) False or misleading label
>
> If its labeling is false or misleading in any particular. . .
>
> (f) Directions for use and warnings on label
>
> Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users[.]...

. . . .

(j) Health-endangering when used as prescribed

> If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

. . . .

30. Licensee knew or reasonably should have known the following regarding the Clindamycin prescription:

a. The original prescription was for an elderly resident of a long term care facility;

b. The original prescription prescribed a seven (7) day course of antibiotic therapy with no refills;

c. The prescription was for Clindamycin, an antibiotic known to cause serious, and sometimes fatal, pseudomembranous colitis, an inflammation of the lining of the bowels that interferes with normal bowel function, often associated with an overgrowth of a different bacteria, *clostridium difficille;*

d. Clindamycin is a federal legend drug that requires a valid prescription for dispensing;

f. The refill order received and dispensed on October 28, 2005 did not include the information required for a valid prescription outlined in 4 CSR 220-2.018.

31. The legend drug Clindamycin was dispensed with a label which included the name of a prescriber who had not authorized or ordered the refills in violaion § 338.059, RSMo.

32. Licensee dispensed the legend drug Clindamycin without a valid prescription, and thus violated the professional trust and confidence of the long term care resident, the long term care facility and the prescriber, and caused the pharmacy to violate its professional trust and confidence to the long term care resident, the long term care facility and the prescriber.

33. Licensee's conduct as alleged herein demonstrates a conscious indifference to her professional duty to comply with the standard of care governing the practice of pharmacy to protect the public safety.

34. Licensee's conduct as alleged herein is a gross deviation from the standard of care which reasonable pharmacist would exercise in this situation.

35. Licensee's' conduct as alleged herein constitutes incompetency in the performance of the functions and duties of a pharmacist.

36. Licensee's pharmacy did not have in force policies and procedures to assure that pharmaceuticals dispensed for residents of the long term care facility were always ordered based upon a valid prescription..

37. Cause exists for the Board to discipline Licensee's pharmacist license based upon the conduct as alleged herein, pursuant to §§ 338.055.2(5), (6), (13) and (15), RSMo (2006 Cum. Supp.), which state:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered her or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
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> . . . .
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> (5) Incompetency, ... gross negligence, ...in the performance of the functions or duties of any profession licensed or regulated by this chapter;
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> . . . .
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> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
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> . . . .
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> (13) Violation of any professional trust or confidence;
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> . . . .
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> (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

Joint Agreed Disciplinary Order

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of §621.045.3, Cum. Supp. 2006, RSMo.

38. Licensee's pharmacist license number 041651 is placed on PROBATION for a period of one (1) year ("disciplinary period") effective immediately upon the date the Board enters and finalizes this Settlement Agreement. During Licensee's probation, Licensee shall be entitled to engage in the practice of pharmacy under Chapter 338, RSMo, provided she adheres to all the terms of this Agreement. The TERMS of Probation shall be:

A. Licensee shall keep the Board apprised of her current home and work addresses and telephone numbers. If at any time Licensee is employed by a temporary employment agency or maintains employment that requires frequent daily or weekly changes of work locations she must provide the Board with all scheduled places of employment in writing prior to any scheduled work time.

B. Licensee shall pay all required fees for licensing to the Board and shall renew her license prior to October 31 of each licensing year.

C. Licensee shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

D. Licensee shall make herself available for personal interviews to be conducted by a member of the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Licensee will be notified and given sufficient time to arrange these meetings.

E. Licensee's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Order/Agreement.

F. The parties to this settlement agreement understand that the Board of Pharmacy will maintain this settlement agreement as an open and public record of the Board as provided in Chapters 338, 610, and 620, RSMo.

G. If, after disciplinary sanctions have been imposed, the Licensee ceased to keep her Missouri license current or fails to keep the Board advised of her current place of employment and residence, such periods shall not be deemed or taken as any part of the time of discipline so imposed.

1. If, after disciplinary sanctions have been imposed, the Licensee begins employment as a pharmacist or technician outside the State of Missouri, such periods shall not be deemed or taken as any part of the time of discipline so imposed. Licensee may petition the Board to seek a waiver of any portion of this requirement by making such a request in written form to the Board for its consideration. No exception will be made to this requirement without prior Board approval.

2. If Licensee leaves the State of Missouri for more than 30 consecutive days, such periods shall not be included as part of the time of discipline so imposed.

H. Licensee shall provide all current and future pharmacy and drug distributor employers and pharmacist/manager-in-charges a copy of this disciplinary order/agreement within five (5) business days of the effective date of discipline or the beginning date of each employment. If at any time Licensee is employed by a temporary employment agency she must provide each pharmacy and drug distributor employer and pharmacist/manager-in-charge a copy of this disciplinary order/agreement prior to or at the time of any scheduled work assignments.

I. Licensee shall not serve as a preceptor for interns.

J. Licensee shall not serve as a pharmacist-in-charge or in a supervisory capacity without prior approval of the Board.

K. Licensee shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months, beginning six (6) months after this Order/Agreement becomes effective, stating truthfully whether or not she has complied with all terms and conditions of her disciplinary order.

L. Licensee shall complete ten (10) additional hours of continuing education, in addition to the number of hours required by law for renewal of Licensee's license. Any hours acquired to fulfill the requirements of this section must be completed after the effective date of the final order of discipline.

The additional continuing education hours must be in the area(s) of Long Term Care Pharmacy. Licensee shall submit the required additional continuing education to the Board office before the end of the disciplinary period.

The ten hours of continuing education described in this section 1L shall be completed during the probationary period, but not later than sixty (60) days prior to the end of the probationary period.

39. The terms of this settlement agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

40. Upon the expiration of said disciplinary period, Licensee's license as a pharmacist in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Licensee has violated any term or condition of this settlement agreement, the Board may, in its

discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Licensee.

41. No order shall be entered by the Board pursuant to the preceding paragraph of this settlement agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

42. If the Board determines that Licensee has violated a term or condition of this settlement agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this settlement agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this settlement agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this settlement agreement has occurred.

43. Licensee hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former Board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees

and expenses, including any claims pursuant to §536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this settlement agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this settlement agreement in that it survives in perpetuity even in the event that any court of law deems this settlement agreement or any portion of it void or unenforceable.

44. Licensee understands that she may, either at the time the settlement agreement is signed by all parties, or within fifteen (15) days thereafter, submit the agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for disciplining Licensee's license. If Licensee desires the Administrative Hearing Commission to review this Agreement, Licensee may submit its request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65101.

45. If Licensee requests review, this settlement agreement shall become effective on the date the Administrative Hearing Commission issues its order finding that the settlement agreement sets forth cause for disciplining Licensee's license. If Licensee does not request review by the Administrative Hearing Commission, the settlement agreement goes in to effect 15 days after the document is signed by the Executive Director of the Board.

46. All parties to bear their own attorneys' fees and costs with no Commission fees or costs being assessed against Licensee.

LICENSEE

Debra Schoen

Debra Schoen, R.Ph.
Pharmacist
Fitzpatrick Pharmacy

Date 6-18-2008

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